



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/529,128	06/30/2000	GRAHAM FRANCOIS DUIRS	08059-0001	2910

22852 7590 11/21/2006

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER

GILBERT, ANDREW M

ART UNIT	PAPER NUMBER
----------	--------------

3767

DATE MAILED: 11/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

NT

Office Action Summary	Application No. 09/529,128	Applicant(s) DUIRS, GRAHAM FRANCOIS	
	Examiner Andrew M. Gilbert	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 August 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11-14 and 17-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-14 and 17-19 is/are rejected.
- 7) ☒ Claim(s) 7 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/20/2006 has been entered.

Specification

2. The use of the trademark "Velcro" on pg 8, ln8 has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner is unsure whether by claim amendment the Applicant has intended to make claim 8 an independent claim or dependent upon claim

Art Unit: 3767

1. Furthermore, the Examiner is unsure as to the scope of claim limitations of “a substance delivery device” of claim 1 that the Applicant is intending to reference in claim 8. For example, the substance delivery device already recites two pod attached to each resilient arm. The Examiner is unsure if the Applicant is intending to reference these pods from claim 1 in claim 8 because claim 8 additionally recites a pod. The Examiner strongly suggests clarifying the matter and if the Applicant intends claim 8 to be independent to explicitly recited in claim 8 each and every limitation intended for recitation from claim 1. Lastly, the Examiner notes that claim 8 should at least read “A pod ...” instead of “The pod ...” on ln 1.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-6, 8-9, 12-14, 17-19 rejected under 35 U.S.C. 102(b) as being anticipated by Sopena Quesada (4353363). Sopena Quesada discloses an internal substance delivery device for insertion into a body cavity (Fig 1), the device includes a support frame (1) having at least two resilient arms (3; Figs 1-3) which retain the device in the body cavity, wherein each resilient arm is capable of receiving and releasing a

Art Unit: 3767

separate pod (5; Figs 4-6) capable of releasing a substance into the body cavity (col 1, Ins 14-28; col 2, Ins 7-35), and wherein the at least two resilient arms are biased outward from a central section (Figs 1-3, 10-16) of the support frame; wherein the substance is a drug (col 1, Ins 14-28; col 2, Ins 7-35; wherein the Examiner notes copper ions perform a spermicidal function on the spermatozoa and thus are considered by the Examiner as being a drug); wherein the device is an intra-vaginal release device (Figs 1-3); wherein the substance is released from the pod through osmosis (col 1, Ins 14-28; col 2, Ins 7-35); wherein the pod is rounded (col 1, Ins 14-28; col 2, Ins 7-35; Figs 4-6); wherein at least one of the pods is flexibly attached to a corresponding arm (col 1, Ins 14-28; col 2, Ins 7-35; Figs 1-6); wherein the support frame is in the form of a wish bone (Figs 1-3); wherein the at least two resilient arms are sufficiently pliable to be moved together to allow the substance delivery device to be effectively compressed (Figs 10-16); wherein the at least two resilient arms are capable of interlocking for removal or insertion (Figs 10-16); wherein the support frame includes a locator (10) to enable the substance delivery device to be readily located and removed from in situ. The Examiner strongly recommends structurally defining the Applicant's pod structure. For example, adding structure defining the pod as a fluid holding reservoir holding with a fluid rate releasing controlling membrane that is fluidly filled separate from the support frame.

7. Claims 1-3, 5-6, 8-9, 12-14, 17-19 rejected under 35 U.S.C. 102(e) as being anticipated by Anderson et al (5816248). Anderson et al discloses an internal

Art Unit: 3767

substance delivery device for insertion into a body cavity (Abstract), the device includes a support frame (38) having at least two resilient arms (48, 58) which retain the device in the body cavity, wherein each resilient arm is capable of receiving and releasing a separate pod (54, 64) capable of releasing a substance into the body cavity (Abstract, col 3, lns 52-67; col 4, lns 18-col 5, lns 37, especially col 5, lns 4-37), and wherein the at least two resilient arms are biased outward from a central section (Fig 3) of the support frame; wherein the substance is a drug (Abstract, col 3, lns 52-67; col 4, lns 18-col 5, lns 37); wherein the device is an intra-vaginal release device (Abstract, col 3, lns 52-67; col 4, lns 18-col 5, lns 37); wherein the pod is rounded (Fig 3; 54, 64); wherein at least one of the pods is flexibly attached to a corresponding arm (Fig 3; Abstract, col 3, lns 52-67; col 4, lns 18-col 5, lns 37); wherein the support frame is in the form of a wish bone (Fig 3); wherein the at least two resilient arms are sufficiently pliable to be moved together to allow the substance delivery device to be effectively compressed (Abstract, col 3, lns 52-67; col 4, lns 18-col 5, lns 37); wherein the at least two resilient arms are capable of interlocking for removal or insertion (Abstract, col 3, lns 52-67; col 4, lns 18-col 5, lns 37); wherein the support frame includes a locator (68; Abstract, col 3, lns 52-67; col 4, lns 18-col 5, lns 37) to enable the substance delivery device to be readily located and removed from in situ. The Examiner strongly recommends structurally defining the Applicant's pod structure. For example, adding structure defining the pod as a fluid holding reservoir holding with a fluid rate releasing controlling membrane that is fluidly filled separate from the support frame.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sopena Quesada. Sopena Quesada discloses the invention substantially as claimed except for expressly disclose the support frame being made out of nylon. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to make the support frame out of nylon because the Applicant has not disclosed that making the support frame out of nylon provides an advantage, is used for a particular purpose, or solves a stated problem. Furthermore, one of ordinary skill in the art would have expected the Applicants invention to perform equally well with the support frame material of Sopena Quesada because the material performs substantially the same function in substantially the same manner. Therefore, it would have been an obvious matter of design choice to modify Sopena Quesada to obtain the invention as specified in claim 11.

10. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. Anderson et al discloses the invention substantially as claimed except for expressly disclose the support frame being made out of nylon. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to make the support frame out of nylon because the Applicant

Art Unit: 3767

has not disclosed that making the support frame out of nylon provides an advantage, is used for a particular purpose, or solves a stated problem. Furthermore, one of ordinary skill in the art would have expected the Applicants invention to perform equally well with the support frame material of Anderson et al because the material performs substantially the same function in substantially the same manner. Therefore, it would have been an obvious matter of design choice to modify Anderson et al to obtain the invention as specified in claim 11.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1-3, 6 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. (6770288).

Although the conflicting claims are not identical, they are not patentably distinct from

Art Unit: 3767

each other because the Applicant is claiming similar subject matter including a substance dispenser attached to a supporting structure, the substance dispenser being a vane or gill impregnated with a drug which one of ordinary skill in the art can consider as a pod capable of releasing a substance.

Response to Arguments

13. Applicant's arguments with respect to claims 1-9, 11-14, 17-19 have been considered but are moot in view of the new ground(s) of rejection.

Allowable Subject Matter

14. Claim 7 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Livesay et al (4572162).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571) 272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3767

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Andrew Gilbert

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

